APR 2 7 2005

K050987

Section 10: Summary

510(k) Summary

Prepared: February 9, 2005

Submitter:

Company Name:	Canon USA, Inc. (U.S. agent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Ms. Sheila Driscoll
Phone Number:	(516) 328-5602
Fax Number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40EG
Classification Name:	MQB, Solid State X-ray Imager
Regulation Number:	892.1650
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40G
Classification Name:	MQB, Solid State X-ray Imager
Regulation Number:	892.1650/892.1630
FDA 510(k) #:	K023750

Description Of Device:

The Canon digital radiography CXDI-40EG is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon digital radiography CXDI-40EG is different from CXDI-40G in the following respect:

- The CXDI-40EG itself is a component without a control PC. Using a general purpose computer with appropriate specifications and the designated system software installed in it, as a control PC, the CXDI-40G achieves performance stated herein (such as image capturing, DICOM transfer and etc.) predicate devices.

The CXDI-40EG can be characterized as almost an equivalent model to the CXDI-40G with a new software version and with a different interface of control PC. The sensor element of the CXDI-40EG has identical characteristics to the CXDI-40G. The images taken with the CXDI-40EG will be equivalent to the CXDI-40G.

Intended Use:

Digital radiography CXDI-40EG provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

Descriptive Comparison:

The predicate devices are the digital radiography CXDI-40G cleared under Document Number K023750 on November 22, 2002.

The CXDI-40EG's technical specifications (including image size, pixel pitch, number of pixels), imaging principle, physical characteristics and intended use are the same as those of CXDI-40G.

Regarding the software:

- The system software for controlling CXDI-40EG is released as V6.3.
- V6.3 includes some changes from V5.0.
- The main changes of the V6.3 are the addition of the control of CXDI-40EG sensor and some change of GUI.
- V5.0 was first introduced and cleared under K023750 and is currently used in Canon models CXDI-40EG.

Based on the information in this submission, similarity to the predicate devices (the Canon digital radiography CXDI-40G), and the results of our design control activities, it is our opinion that the Canon digital radiography CXDI-40EG described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Canon, Inc.
% Mr. Williams J. Sammons
Reviewer
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
RESEARCH TRIANGLE PARK NC 27709

AUG 23 2013

Re: K050987
Trade/Device Name: CXDI-40EG
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 18, 2005
Received: April 19, 2005

Dear Mr. Sammons:

This letter corrects our substantially equivalent letter of April 27, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050987

Device Name: CXDI-40EG

Indications For Use:

DIGITAL RADIOGRAPHY CXDI-40EG is used to directly capture and convert conventional projection X-ray images to digital images. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050987